DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administra
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

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December 17, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bobby E. Prather, President
Prather Welding Supply, Inc.
P. O. Box 1727
3015 Heritage Place
Milledgeville, Ga. 31061

WARNING LETTER

Dear Mr. Prather:

An inspection of your medical oxygen transfilling facility was conducted on November 21-22, 1996, by investigator Robert P. Neligan. Investigator Neligan documented several significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal, Food , Drug and Cosmetic Act (the Act).

The following deviations were observed:

- Failure to assure that the [redacted] Oxygen Analyzer is accurate to 1% for purity analysis.
- Failure to calibrate the oxygen analyzer on each day of use.
- Failure to assay a cylinder from each batch for purity, prior to release.
- Failure to establish lot codes for each batch produced.
- Failure to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the purity that it purports or is represented to possess.

At the conclusion of the inspection, Investigator Neligan issued his Inspectional Observations (FDA 483) to and discussed his findings with you. Neither the above listed deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility. You indicated in the close out discussion that you would be ordering a Servomex 570A oxygen analyzer, and that you would cease operations until the analyzer arrived.

You should take all necessary steps to correct all violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your response should be addressed to Barbara A. Wood, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District